Filed for intro on 01/11/2001

HOUSE BILL 123
By Turner (Dav)

AN ACT to amend Tennessee Code Annotated, Title 47; Title 53; Title 56; Title 63 and Title 71, relative to prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 71, Chapter 5, is amended by adding Sections 2 through 6, inclusive, as a new part to be appropriately designated.

SECTION 2. (a) The Tennessee Rx Program, referred to in this part as the "program," is established to reduce prescription drug prices for residents of the State. The program is designed for the State to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the State shall serve as a pharmacy benefit manager in establishing rebates and discounts on behalf of qualified residents.

(b) The general assembly finds that affordability is critical in providing access to prescription drugs for Tennessee residents. This part is enacted by the general assembly to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Tennessee residents, thereby increasing the overall health of Tennessee residents, promoting healthy communities and protecting the public health and welfare. It is not the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription

drug benefit plans that provide benefits comparable to those made available to qualified Tennessee residents under this part.

(c) As used in this part, unless the context otherwise indicates, the following terms have the following meanings:

(1) "Average wholesale price" means the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug-pricing file.

(2) "Commissioner" means the commissioner of health.

(3) "Department" means the department of health.

(4) "Household income" means all income received by all persons of a household in a calendar year while members of the household.

(5) "Initial discounted price" means a price that is less than or equal to the average wholesale price, minus six percent (6%), plus the dispensing fee provided under the medical assistance program under this title.

(6) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20.

(7) "Participating retail pharmacy" or "retail pharmacy" means a retail pharmacy located in this State, or another business licensed to dispense prescription drugs in this State, that participates in the program and that provides discounted prices to residents as provided in subsection (f).

(8) "Pharmacy benefit manager" means an entity that procures prescription drugs at a negotiated rate under a contract.

(9) "Prescription drug" means any item which federal law prohibits dispensing without a prescription from a licensed doctor, dentist, optometrist or veterinarian.

(10) "Qualified resident" means a resident of the State who is a participant in the low-cost prescription drug program established by Section 5 or who lacks access to public or private health insurance coverage, as such coverage is defined in Tennessee Code Annotated, Section 56-7-2802, that provides prescription drug coverage as a benefit.

(11) "Secondary discounted price" means a price that is equal to or less than the initial discounted price minus the amount of any rebate paid by the State to the participating retail pharmacy.

(12) "Wholesale price" means the average price paid by a wholesaler to a pharmaceutical manufacturer for a product distributed for retail sale. "Wholesale price" includes a deduction for any customary prompt payment discounts.

(d) A drug manufacturer or labeler that sells prescription drugs in this State through the elderly low-cost drug program under Section 5 or any other publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the department for this program. The rebate agreement must require the manufacturer or labeler to make rebate payments to the State each calendar quarter or according to a schedule established by the department.

(e) The commissioner shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this subsection.

(1) The commissioner shall take into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8, the average wholesale price of prescription drugs and any other information on prescription drug prices and price discounts.

(2) The commissioner shall use the commissioner's best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 United States Code, Section 1396r-8.

(3) With respect to the rebate taking effect no later than October 1, 2002, the commissioner shall use the commissioner's best efforts to obtain an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the federal government.

(f) Any participating retail pharmacy that sells prescription drugs covered by a rebate agreement pursuant to subsection (d) shall discount the retail price of those drugs sold to qualified residents.

(1) The department shall establish discounted prices for drugs covered by a rebate agreement and shall promote the use of efficacious and reduced-cost drugs, taking into consideration reduced prices for state and federally capped drug programs, differential dispensing fees, administrative overhead and incentive payments.

(2) Beginning January 1, 2002, a participating retail pharmacy shall offer the initial discounted price.

(3) No later than October 1, 2002, a participating retail pharmacy shall offer the secondary discounted price.

(4) In determining the amount of discounted prices, the department shall consider an average of all rebates provided pursuant to subsection (e), weighted by sales of drugs subject to these rebates over the most recent twelve- (12) month period for which the information is available.

(g) The requirements of this subsection apply to participating retail pharmacies.

(1) The Tennessee board of pharmacy shall adopt rules requiring disclosure by participating retail pharmacies to qualified residents of the amount of savings provided as a result of the program. The rules must consider and protect information that is proprietary in nature.

(2) The department may not impose transaction charges under this program on retail pharmacies that submit claims or receive payments under the program.

(3) A participating retail pharmacy shall submit claims to the department to verify the amount charged to qualified residents under subsection (f).

(4) On a weekly or biweekly basis, the department shall reimburse a participating retail pharmacy for discounted prices provided to qualified residents under subsection (f) and professional fees, which shall be set by the commissioner. The amount of the initial professional fee shall be set at three dollars ($3.00) per prescription.

(5) The department shall collect utilization data from the participating retail pharmacies submitting claims necessary to calculate the amount of the rebate from the manufacturer or labeler. The department shall protect the confidentiality of all information subject to confidentiality protection under state or federal law, rule or regulation.

(h) The names of manufacturers and labelers who do not enter into rebate agreements pursuant to this part are public information. The department shall release this information to healthcare providers and the public. The department shall impose prior authorization requirements in the medical assistance program under this title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers.

(i) Discrepancies in rebate amounts shall be resolved using the process established in this subsection.

(1) If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer or labeler, the department, at the department's expense, may hire a mutually agreed-upon independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the department for any additional amount due.

(2) If there is a discrepancy against the interest of the manufacturer or labeler in the information provided by the department to the manufacturer or labeler regarding the

manufacturer's or labeler's rebate, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or refund to the manufacturer any excess payment made by the manufacturer or labeler.

(3) Following the procedures established in subdivision (1) or (2), either the department or the manufacturer or labeler may request a hearing before an administrative law judge. Supporting documentation must accompany the request for a hearing.

(j) The Tennessee Rx Dedicated Fund, referred to in this section as the "fund," is established to receive revenue from manufacturers and labelers who pay rebates as provided in subsection (e) and any appropriations or allocations designated for the fund. The purposes of the fund are to: reimburse retail pharmacies for discounted prices provided to qualified residents pursuant to subsection (f); to reimburse the department for contracted services, administrative and associated computer costs, professional fees paid to participating retail pharmacies and other reasonable program costs; and to benefit the elderly low-cost drug program under Section 5. Moneys from the fund may be expended to fund activities authorized by this part. Any revenues deposited in this reserve shall remain in the reserve until expended for purposes consistent with this part, and shall not revert to the general fund on any June 30. Any excess revenues on interest earned by such revenues shall not revert on any June 30, but shall remain available for appropriation in subsequent fiscal years. Surplus funds in the fund may be used only for the benefit of the program or surplus funds may also be transferred to the elderly low-cost drug program established under Section 5.

(k) The department shall report the enrollment and financial status of the program to the general assembly by the second week in January each year.

(l) The department shall establish simplified procedures for determining eligibility and issuing Tennessee Rx enrollment cards to qualified residents and shall undertake outreach efforts to build public awareness of the program and maximize enrollment of qualified residents. The commissioner shall set standards for an application process and standards for determining access to such insurance by rule in accordance with the provisions of Tennessee Code Annotated, title 4, chapter 5. The department may adjust the requirements and terms of the program to accommodate any new federally-funded prescription drug programs.

(m) The department may contract with a third-party or third-parties to administer any or all components of the program, including, but not limited to, outreach, eligibility, claims, administration and rebate recovery and redistribution.

(n) The department shall administer the program and other medical and pharmaceutical assistance programs under this title in a manner that is advantageous to the programs and to the enrollees in those programs. In implementing this subsection the department may coordinate the other programs and this program and may take actions to enhance efficiency, reduce the cost of prescription drugs and maximize the benefits to the programs and enrollees, including providing the benefits of this program to enrollees in other programs.

(o) The department may adopt rules to implement the provisions of this section in accordance with the provisions of Tennessee Code Annotated, title 4, chapter 5.

(p) The department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this part.

SECTION 3. The prescription drug advisory commission, referred to in this part as the "commission," is established to review access to and the pricing of prescription drugs for residents of the State, to advise the commissioner on prescription drug pricing and to provide periodic reports to the commissioner, the governor and the general assembly.

(a) The commission consists of the following twelve (12) members:

(1) Three (3) members of the public, appointed by the speaker of the senate, one of whom must represent the interests of senior citizens. Of the initial appointees, one (1) must be appointed for a two- (2) year term and (two) 2 for three-(3) year terms;

(2) Three (3) members of the public, appointed by the speaker of the house of representatives, one of whom must represent the interests of senior citizens. Of the initial appointees, one (1) must be appointed for a two- (2) year term and (two) 2 for three- (3) year terms;

(3) Two (2) members of the health-care community who are authorized by the laws of this State to prescribe drugs, appointed by the governor. Of the initial appointees, one (1) must be appointed for a two- (2) year term and one for a three- (3) year term;

(4) Two (2) pharmacists, appointed by the governor. Of the initial appointees, one (1) must be appointed for a two- (2) year term and one (1) for a three- (3) year term. To be appointed to and remain on the commission, each pharmacist must:

(A) Be licensed to practice pharmacy and be engaged in the practice of retail pharmacy in this State;

(B) Have at least five (5) years of experience in this State as a licensed pharmacist; and

(C) Be a resident of this State; and

(5) The director of the bureau of TennCare and the commissioner of health, or their designees, who shall serve as ex officio, nonvoting members.

(b) With the exception of the initial appointees, all members of the commission serve for terms of three (3) years and may be reappointed. With the exception of the pharmacist members, if the profession or qualifications of a commission member changes during the term of commission membership, the member may continue to complete the term for which the appointment was made.

(c) The commission shall meet at least four (4) times per year. The members shall select a chair from among the members. Additional meetings may be called by the chair.

(d) The duties of the commission include the following:

(1) To review access to prescription drugs for residents of the State, including, but not limited to, pricing and affordability information;

(2) To advise the commissioner on access to prescription drugs and prescription drug prices, including, but not limited to, insurance and third-party payments for prescription drugs, the need for maximum retail prices, and, if maximum retail prices are established, the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail prices of selected drugs and the procedures for phasing out or terminating maximum retail prices;

(3) To advise the commissioner on the adoption of rules necessary to implement this part; and

(4) To report to the commissioner, the general assembly and the governor by April 1, 2002, and annually thereafter by the second week in January, including in the report any recommendations for action regarding access to and the pricing of prescription drugs.

(e) The department shall provide staffing for the commission.

(f) Public members not otherwise compensated by their employers or, other entities whom they represent, are entitled to receive reimbursement for their attendance at authorized meetings of the commission in accordance with the rules promulgated by the commissioner of finance and administration and approved by the attorney general and reporter.

(g) In performing its duties, the commission shall work with the department, the board of pharmacy and the department of commerce and insurance.

SECTION 4. In order to achieve the public health purposes listed in Section 2 and 8 of this act, maximum retail prices for prescription drugs sold in Tennessee may be established pursuant to this section.

(a) The following provisions apply to determinations regarding maximum retail prices for prescription drugs and to the procedures for establishing those prices.

(1) By July 1, 2003, the department shall adopt rules establishing the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail prices of selected drugs and the procedures for phasing out or terminating maximum retail prices. Prior to adopting rules pursuant to this section, the commissioner shall consult with and consider the recommendations of the commission regarding the rules.

(2) By January 1, 2004, the commissioner shall determine whether the cost of prescription drugs provided to qualified residents under the Tennessee Rx Program pursuant to Section 2 is reasonably comparable to the lowest cost paid for the same drugs delivered or dispensed in the State. In making this determination the following provisions apply.

(A) The commissioner shall review prescription drug use in the medical assistance program using data from the most recent six- (6) month period for which data is available.

(B) Using the data reviewed in subdivision (A), the commissioner shall determine the one hundred (100) drugs for which the most units were provided and the one hundred (100) drugs for which the total cost was the highest.

(C) For each prescription drug listed in subdivision (B), the commissioner shall determine the cost for each drug for qualified residents provided those

drugs under the Tennessee Rx Program on a certain date. The average cost for each such drug must be calculated.

(D) For each prescription drug listed in subdivision (C), the commissioner shall determine the lowest cost for each drug paid by any purchaser on the date that is used for subparagraph (3) delivered or dispensed in the State, taking into consideration the federal supply schedule and prices paid by pharmaceutical benefits managers and by large purchasers and excluding drugs purchased through the Tennessee Rx Program. The average cost for each such drug must be calculated.

(E) If the average cost for one (1) or more prescription drugs under the Tennessee Rx Program as determined in subdivision (C) is not reasonably comparable to the average lowest cost for the same drug or drugs as determined in subdivision (D), the commissioner shall establish maximum retail prices for any or all prescription drugs sold in the State. Maximum prescription drug prices established under this subparagraph shall take effect July 1, 2004.

(3) In establishing maximum retail prices under this paragraph, the commissioner shall consider the advice of the commission and shall follow procedures set forth by rules adopted by the department.

(b) In making a determination under this section the commissioner may rely on pricing information on a selected number of prescription drugs if that list is representative of the prescription drug needs of the residents of the State and is made public as part of the process of establishing maximum retail prices.

(c) The commissioner may take actions that the commissioner determines necessary if there is a severe limitation or shortage of or lack of access to prescription drugs in the State that could threaten or endanger the public health or welfare.

(d) A retailer of prescription drugs may appeal the maximum retail price of a prescription drug established pursuant to this section in accordance with the Uniform Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

(e) A violation of the maximum retail prices established under this section is a violation of the Tennessee Unfair Trade Practices Act and shall be subject to enforcement in the same manner violations of Sections 47-25-101 and 47-25-102.

SECTION 5.

(a) (1) The department of health may conduct a program to provide low-cost prescription and nonprescription drugs, medication and medical supplies to disadvantaged, elderly and disabled individuals.

(2) An individual is eligible for assistance under the program established by this section if the individual meets the income requirements of subdivision (b)(2) and is:

(A) At least sixty-two (62) years of age; or

(B) Nineteen (19) years of age or older and determined to be disabled by the standards of the federal social security program. In order to be eligible the individual must also be a legal resident of the State at the time the application is filed. An individual does not qualify as eligible if the individual receives medical assistance pursuant to Tennessee Code Annotated, title 71, chapter 5, part 1.

(3) The commissioner shall provide for sufficient personnel to ensure efficient administration of the program. The extent and the magnitude of the program shall be determined by the commissioner on the basis of the calculated need of the recipient population and the available funds. The department may not spend more on this program than is available through appropriations from the general fund, dedicated revenue, federal or other grants and other established and committed funding sources. The commissioner may accept, for the purposes of carrying out this program, federal funds appropriated under any federal law relating to the furnishing of free or low-cost

drugs to disadvantaged, elderly and disabled individuals and may take such actions as is necessary for the purposes of carrying out that federal law and may accept from any other agency of government, individual, group or corporation such funds as may be available to carry out this chapter.

(b) The commissioner may adopt rules relating to the conduct of this program. These rules must be adopted in accordance with the Uniform Administrative Procedures Act, title 4, chapter 5, and shall be related to the following aspects of this program:

(1) The kinds of prescription and nonprescription drugs, medications and medical supplies that may be made available through the operation of this program. Drugs and medications shall be provided for the conditions and illnesses provided in this subsection.

(A) The basic component of the program shall provide drugs and medications for cardiac conditions and high blood pressure, diabetes, arthritis, anticoagulation, hyperlipidemia, osteoporosis, chronic obstructive pulmonary disease and asthma, incontinence, thyroid diseases, glaucoma, Parkinson's disease, multiple sclerosis and amyotrophic lateral sclerosis.

(B) In the supplemental component of the program, drugs and medications shall include all prescription drugs and medications provided under the medical assistance program under this title with the exception of drugs and medications provided by the basic component of the program under sub-item (A).

(2) Income eligibility of individuals must be determined by this subsection and by reference to the federal nonfarm income official poverty level, as defined by the federal Office of Management and Budget and revised annually in accordance with the United States Omnibus Budget and Reconciliation Act of

1981, Section 673, Subsection 2. If the household income, as defined in Section 2 (c)(4), is less than one hundred eighty-five percent (185%) of the federal poverty line applicable to the household, the individual is eligible for the basic and the supplemental program. Individuals are also eligible for the basic program and the supplemental program prescription drugs and medications if the household spends at least forty percent (40%) of its income on unreimbursed direct medical expenses on prescription drugs and the household income is not more than twenty-five percent (25%) higher than the levels specified in this subsection. For the purposes of this subsection, the cost of drugs provided to a household under this section is considered a cost incurred by the household for eligibility determination purposes.

(3) Specifications for the administration and management of the program, which may include, but not be limited to program objectives, accounting and handling practices, supervisory authority and evaluation methodology.

(4)

(A) The method of prescribing or ordering these drugs, which may include, but is not limited to, the use of standard or larger prescription refill sizes so as to minimize operational costs and to maximize economy. Unless the prescribing physician indicates otherwise, the use of generic or chemically equivalent drugs is required, provided that these drugs are of the same quality and have the same mode of delivery as is provided to the general public, consistent with good pharmaceutical practice. Each prescription filled shall be for a supply of ninety (90) days unless the prescribing physician or the recipient requests otherwise.

(B) The commissioner may establish the amount of payment to be made by recipients toward the cost of prescription or nonprescription

drugs, medication and medical supplies furnished under this program; provided that, for persons at or below one hundred eighty-five percent (185%) of the federal poverty line, the total cost for any covered purchase of a prescription or nonprescription drug or medication provided under the basic component of the program does not exceed twenty percent (20%) of the price allowed for that prescription under program rules or two dollars ($2.00). For the supplemental component of the program, the total cost paid by the individual for any covered purchase of a prescription drug or medication may not exceed the cost of the program for that drug or medication minus the two dollars ($2.00) paid by the program.

(5) The manner in which qualified residents shall apply to the department or to any agency designated by the commissioner in order to participate in the Tennessee Rx program. Eligible individuals shall obtain from the department a Tennessee Rx enrollment card.

(6) Such other rules as may be necessary to efficiently and effectively manage and operate a program within the intent of this section.

SECTION 6. (a) Effective January 1, 2002, payment must be denied for drugs from manufacturers that do not enter into a rebate agreement with the department for prescription drugs included in the list of approved drugs under this part. Each agreement must provide that the pharmaceutical manufacturer make rebate payments for both the basic and supplemental components of the program to the department according to the following schedule:

(1) For the quarters beginning January 1, 2002, the rebate percentage is equal to the percentage recommended by the federal HealthCare Financing Administration of the manufacturer's wholesale price for the total number of dosage units of each form and strength of a prescription drug that the department reports as reimbursed to providers of prescription drugs, provided payments are not due until thirty (30) days following the

manufacturer's receipt of utilization data supplied by the department, including the number of dosage units reimbursed to providers of prescription drugs during the period for which payments are due.

(2) Beginning October 1, 2002, the department shall seek to achieve an aggregate rebate amount from all rebate agreements that is six (6) percentage points higher than that required by subdivision (1) of this subsection, provided such rebates result in a net increase in the rebate revenue available to the elderly low-cost drug program. In the event the department is not able to achieve the rebate amount required by this paragraph without compromising the best interest of recipients of the elderly low-cost drug program, it shall report to the standing committees of each house of the general assembly having jurisdiction over health and human services matters and the standing finance ways and means committees of the senate and the house of representatives.

(3) Upon receipt of data from the department, the pharmaceutical manufacturer shall calculate the quarterly payment. If a discrepancy is discovered, the department may, at its expense, hire a mutually agreed-upon independent auditor to verify the pharmaceutical manufacturer's calculation. If a discrepancy is still found, the pharmaceutical manufacturer shall justify its calculation or make payment to the department for any additional amount due. The pharmaceutical manufacturer may, at its expense, hire a mutually agreed-upon independent auditor to verify the accuracy of the utilization data provided by the department. If a discrepancy is discovered, the department shall justify its data or refund any excess payment to the pharmaceutical manufacturer. If the dispute over the rebate amount is not resolved, a request for a hearing with supporting documentation must be submitted to an administrative law judge. Failure to resolve the dispute may be cause for terminating the drug rebate agreement and denying payment to the pharmaceutical manufacturer for any drugs.

Any prescription drug of a manufacturer that does not enter into an agreement is not reimbursable unless the department determines the prescription drug is essential. All prescription drugs of a pharmaceutical manufacturer that enters into an agreement pursuant to this subsection that appear on the list of approved drugs under this program must be immediately available and the cost of the drugs must be reimbursed and is not subject to any restrictions or prior authorization requirements, except as provided in this paragraph. If the commissioner establishes maximum retail prices for prescription drugs pursuant to section 4 of this act, the department shall adopt rules for the elderly low-cost drug program requiring the use of a drug formulary and prior authorization for the dispensing of certain drugs to be listed on a formulary.

(b) Beginning January 1, 2001, all manufacturers and labelers of drugs that participate in the medical assistance program under this title shall participate in the drug rebate program under this section. For the purposes of this subsection, "labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20.

SECTION 7. Tennessee Code Annotated, Title 47, is amended by adding Sections 8 through 11, inclusive as a new part 18.

SECTION 8. (a) The general assembly makes the following findings:

(1) Pharmaceutical companies are charging the citizens of Tennessee excessive prices for prescription drugs, denying Tennessee citizens access to medically necessary healthcare and thereby threatening their health and safety. Many Tennessee citizens are admitted to or treated at hospitals each year because they cannot afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others must enter expensive institutional care settings because they cannot afford their necessary prescription drugs that could have supported them outside of an institution. All

Tennessee citizens are threatened by the possibility that when they need medically necessary prescription drugs most they may be unable to afford their doctor's recommended treatment.

(2) Citizens of Tennessee and other Americans pay the highest prices in the world for prescription drugs, prices that result in extremely high profits for pharmaceutical companies.

(3) Prescription drug costs represent the fastest growing item in healthcare and are a driving force in rapidly increasing hospital costs and insurance rates.

(4) Excessive pricing for prescription drugs threatens Tennessee's ability to assist with the healthcare costs of Tennessee citizens, undermines the financial capacity of Tennessee communities to meet the educational needs of Tennessee children, hurts the ability of the Tennessee business community to provide health insurance coverage to Tennessee's work force and has a negative effect on Tennessee's economy. The general assembly finds that affordability is critical in providing access to prescription drugs for Tennessee residents.

(b) It is the intent of the general assembly to provide access for all Tennessee citizens to medically necessary prescription drugs at the lowest possible prices.

(c) This act is enacted by the general assembly as a positive measure to make prescription drugs more affordable for Tennessee residents, thereby increasing the overall health of our families, benefiting employers and employees and the fiscal strength of our society, promoting healthy communities and increasing the public health and welfare.

SECTION 9. Profiteering in prescription drugs is unlawful and is subject to the provisions of this section. The provisions of this section apply to manufacturers, distributors and labelers of prescription drugs.

(a) As used in this part, unless the context otherwise indicates, the following terms have the following meanings:

(1) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20.

(2) "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.

(b) A manufacturer, distributor or labeler of prescription drugs engages in illegal profiteering if that manufacturer, distributor or labeler:

(1) Exacts or demands an unconscionable price;

(2) Exacts or demands prices or terms that lead to any unjust or unreasonable profit;

(3) Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State; or

(4) Intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this State in retaliation for the provisions of this part.

(c) The attorney general and reporter may bring a civil action in chancery court or circuit court for a direct or indirect injury to any person, group of persons, the State or a political subdivision of the State caused by a violation of this part. There is a right to a jury trial in any action brought in chancery court under this section. If the State prevails, the defendant shall pay three (3) times the amount of damages and the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees. For a willful or repeated violation of this section, punitive damages may be awarded. After deduction of the costs of distribution, the damages must be equitably distributed by the State to all injured parties.

(d) Each violation of this section is a civil violation for which the attorney general and reporter may obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount not to exceed one hundred thousand dollars ($100,000), plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

(e) A violation of this section is also a violation of the Unfair Trade Practices Act, Tennessee Code Annotated, Title 47, Chapter 25, Part 1, and shall be subject to enforcement in the same manner as violations of Sections 47-25-101 and 47-25-102.

SECTION 10. The attorney general and reporter, upon the attorney general's own initiative or upon petition of the commissioner of health or of fifty (50) or more residents of the State, shall investigate suspected violations of this part.

The attorney general may require, by summons, the attendance and testimony of witnesses and the production of books and papers before the attorney general related to any such matter under investigation. The summons must be served in the same manner as a summons for witnesses in criminal cases, and all provisions of law related to criminal cases apply to any summons issued under this section so far as they are applicable. All investigations or hearings under this section to which witnesses are summoned or called upon to testify or to produce books, records or correspondence are public or private at the choice of the person summoned and must be held in the county where the act to be investigated is alleged to have been committed, or if the investigation is on petition, it must be held in the county in which the petitioners reside.

The court may by order, upon application of the attorney general, compel the attendance of witnesses, the production of books and papers, including correspondence, and the giving of testimony before the attorney general in the same manner and to the same extent as before the court. Any failure to obey such an order may be punishable by that court as a contempt.

SECTION 11. The State may negotiate and enter into purchasing alliances and regional strategies with the governments of other jurisdictions and with other public and private entities for the purpose of reducing prescription drug prices for residents of the State.

SECTION 12. All appointments under this act shall be completed no later than thirty (30) days following the effective date of this act. The appointing authorities shall notify the commissioner of health upon making their appointments. The commissioner of health shall call the first meeting of the commission within thirty (30) days after notification that appointments have been completed. At the first meeting of the commission, the members shall select a chair from among the members.

SECTION 13. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new section:

Section 71-5-191. (a) Beginning January 1, 2002, all manufacturers and labelers of drugs that participate in the medical assistance program under this part shall participate in the drug rebate program under SECTIONs 2 and 6 of this act.

(b) If the commissioner of health establishes maximum retail prices for prescription drugs pursuant to SECTION 4 of this act, the department shall adopt rules for the medical assistance program requiring additional prior authorization for the dispensing of drugs determined to be priced above the established maximum retail prices. The department shall adopt rules for the medical assistance program requiring additional authorization for the dispensing of drugs provided from manufacturers and labelers who do not enter into agreements with the department under SECTION 2(d) of this act.

(c) With respect to aspects of the medical assistance program operating under a federal waiver for the provisions of services under this part, the provisions of this section shall not take effect unless the federal HealthCare Financing Administration provides

any necessary approvals required under the terms of the waiver or applicable federal law.

(d) For the purpose of this section, "labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal food and drug administration under 21 Code of Federal Regulations, Section 207.20.

SECTION 14. The provisions of this act shall not be construed to be an appropriation of funds and no funds shall be obligated or expended pursuant to this act unless such funds are specifically appropriated by the general appropriations act.

SECTION 15. The commissioner is authorized to promulgate rules and regulations to effectuate the purposes of this act. All such rules and regulations shall be promulgated in accordance with the provisions of Tennessee Code Annotated, title 4, chapter 5.

SECTION 16. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 17. This act shall take effect July 1, 2001, the public welfare requiring it.